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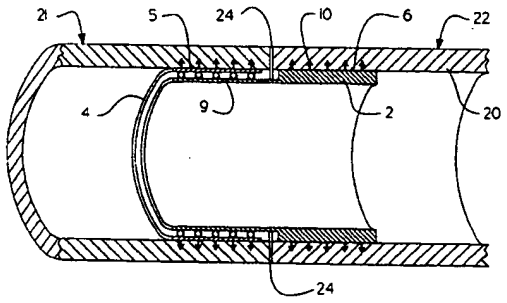
(54) **Apparatus for connecting and closing severed blood vessels.**

(57) A fastener for closing or connecting blood vessels (21,22) has a plurality of miniature barbs (10,37) which pierce the wall (20,26) of the blood vessel (21,22) and anchor the fastener in place. In one embodiment the fastener is comprised of a male member (2) and a female member (4) which are fastened to blood vessel segments with the miniature barbs (10). The male (2) and female (4) members are joined together by inserting the male member (2) into the female member (4) to form a permanent coupling. In another embodiment the fastener is comprised of a ring (36) with miniature barbs (37) on both surfaces ; that is used between the splayed ends of a severed blood vessel (21,22). The device can also be used for opening a blood vessel (51) which has been narrowed by disease or trauma.

Fig.1.



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The invention relates to an apparatus for connecting or closing severed blood vessels, which apparatus can be used as an alternative to suturing.

Many surgical procedures involve partially or totally severed blood vessels which must be reconnected or closed. The conventional method of reconnecting such vessels and closing incisions is by sewing them together with a suitable suture material. Although this procedure has been medically successful, it can involve considerable time during an operation. Thus there is a need for an apparatus which can be used in a method for quickly connecting or closing severed blood vessels. Any device used to connect blood vessels together must be compatible with the human or animal body in which it is used. Since most blood vessels are flexible, it is desirable that any such device also be flexible.

In one embodiment a fastener according to the invention is comprised of a male member and a female member which are fitted together with a one way connector. After the male member has engaged the female member the fastener cannot be disengaged without destroying the coupling. A portion of the exterior of the male member has a plurality of very small projections which are sized to engage a receiving surface on the interior of the female member. The receiving surface is constructed to receive the projections from the male member and make a permanent coupling therebetween. Both the male member and the female member have a plurality of micro miniature barbs on at least a portion of their outer surfaces. Those barbs are positioned to penetrate the walls of the blood vessel and then hold the coupling in place against the blood vessel wall. The coupling may be inserted into the blood vessel by any convenient means. If the blood vessel has been severed or substantially cut open, the fastener's segments could be positioned through the opening created when the blood vessel was cut.

The second preferred embodiment is comprised of a flexible body having one surface from which a plurality of micro miniature barbs extend. The body is sized so as to extend around at least a portion of the inner surface or outer surface of the blood vessel. Preferably the body is a compressible hollow cylinder or a flat sheet which can be rolled to a dimension smaller than the blood vessel, inserted in the blood vessel and then expanded to engage the inside wall of the blood vessel. A preferred way of inserting this embodiment is to wrap the flexible body around a balloon catheter and extend the catheter into the vessel to the location where fastening or closure is required. Then the balloon is inflated to unroll the fastener and press it tightly against the inside wall of the blood vessel.

The invention is illustrated by the accompanying drawings, of which:

Figure 1 is a cross sectional view of a first embodiment of a fastener according to the invention, the fastener being used to close two segments of a severed blood vessel;

Figure 2 is an exploded view of a part of the fastener of Figure 1;

Figure 3 is a side view partially in section of a second embodiment of a fastener according to the invention placed within a blood vessel;

Figure 4 is a side view partially in section of the fastener of Figure 3 placed on the exterior of a blood vessel;

Figure 5 is a perspective view partially in section of the fastener of Figure 3 in a rolled condition around a balloon catheter;

Figure 6 is a perspective view partially in section of the fastener of Figures 3 and 5 in an unrolled expanded condition;

Figure 7 is a cross-sectional view of a third embodiment of a fastener according to the invention, seen with the splayed ends of two segments of a severed blood vessel;

Figure 8 is an enlarged view of a part of the fastener of Figure 7, showing how it operates to close the blood vessel;

Figure 9 is a plan view of the fastener of Figure 7; and

Figure 10 is a cross-sectional view showing a fastener according to the invention used in a blood vessel which has been narrowed by disease or trauma.

Referring to Figures 1 and 2 a first preferred embodiment used as a fastener is comprised of a male member 2 and female member 4 which are connected to form of stent. Both the male member and female member are generally cylindrical. They should be made of a flexible material. On the outer surface 5 of the female member and a first portion of the outer surface 6 of the male member we provide a plurality of micro barbs 10. The micro barbs are sized to extend into the wall 20 of blood vessel segments 21 and 22. The segments may have been completely detached or only partly separated from one another by an incision which created gap 24. The micro barbs are generally comprised of a stem 11 and at least one barb 12 which may be of a triangular configuration as shown in Figures 1 and 2. Alternatively, one could use tiny fish hook structures or other shapes which can be firmly embedded into the blood vessel wall. On the inner surface of the female member 4 and on a second portion 9 of the outer surface of the male member 2 we provide mating fastening members which engage to form a permanent connection between the male member and the female member. In the embodiment of Figure 1 fastening means 16 are generally hemispherical in shape and adapted to receive pods 18 which extend from stems 19 attached to portion 9 of the male member 2. The male member 2 and female member 4 should be made of a flexible biocompatible

material. One suitable material is silicon. Some plastics of the type used for other types of implantable structures may also be appropriate.

In Figures 1 and 2 there is shown a fastening means using a pod on a stem which fits into a hemisphere to form a locked connection. Various other configurations are known in the art which can also be used. For example, one could provide a doughnut shape into which the pods extend rather than the hemisphere 16. Similarly pods 18 could be triangular and inserted into a similarly contoured receiving member.

In Figures 3 and 4 there is shown a second preferred embodiment of a fastener 30 which is comprised of a flexible material having a plurality of barbs 10 extending from one surface 32 of the closure 30. The closure could be positioned as a stent within the blood vessel as shown in Figure 3 so that the barb surface engages and anchors the closure to the inner wall of the blood vessel. Alternatively, this closure can be wrapped around the outside of the blood vessel as shown in Figure 4 so that the barbs penetrate and embed within the outer surface 26 of blood vessel segments 21 and 22.

Preferably the embodiment of Figures 3 and 4, and both the male member and female member of the embodiment shown in Figures 1 and 2, are made of a flexible sheet which can be rolled to a diameter smaller than the inside diameter of the blood vessel. The rolled structure is placed at the juncture point of the vessel to be fastened and then expanded to engage the interior wall of the blood vessel.

In Figure 5 the female member is shown having been rolled to a smaller diameter and placed upon balloon portion 40 of a balloon catheter 42. It should be noticed that the inner surface of the female member 2 is separated from an overlapping portion of the outer surface 6 of the female member by a flap 44 extending from a balloon catheter 42. After the female member is located in the proper position the balloon portion 40 is inflated thereby unrolling the female member 2. As shown in Figure 6 after unrolling the device, micro barbs 10 penetrate the blood vessel wall and anchor the female member in place. The male member 2 is inserted in a similar fashion. However, since the interior surface of the male member is smooth it is not necessary to provide a flap to separate adjacent surfaces of the male member when it is in a rolled position.

Referring to Figures 7, 8 and 9 another embodiment is comprised of a ring shaped body 36 having a plurality of micro miniature barbs 37 on opposite faces 38 and 39 the ends of the blood vessel segments are splayed. Then the inside wall portion of the vessels are pressed against a barbed face. The barbs penetrate the vessels joining them until tissue regrowth takes place. Placing the connector on the inside of the vessel avoids the difficulties associated with ring-and-pin type conenctors. In this embodiment the splayed ends provide a larger passageway for blood flow than in the embodiments of Figures 1 and 3. By holding the vessel open, regrowth of the tissue over the stent would be facilitated while the maximum blood flow rate is maintained. To provide flexibility, score lines 35 may be provided on faces 38 and 39. The ring could also be made of a radially compressible material. Then the ring 36 could be placed in position and caused to expand through use of a balloon catheter as in Figure 6 or as a result of the memory of the material.

The device of the invention can be used to open vessels that have been narrowed from disease or trauma. In Figure 10 is shown a partially occluded blood vessel 50 which has been constructed by deposits 52. The device 60 is inserted with a balloon catheter 42. The balloon portion 40 of the catheter 42 is expanded (see Figure 6) to attach the device to the wall 51 of the vessel 50 at the disease site. Then the balloon portion 42 is deflated and the catheter is removed. The device remains in place to maintain lumen through the diseased site.

In all of the embodiments passageways can be provided in the barbs. By fabricating each of the barbs with a passageway 45 and reservoir 46, shown in broken lines in Figure 8, the barbed face of the closure could act as a surface of microscopic hypodermic needles. Connection of the passageways to a larger reservoir (not shown) would provide a method of local drug delivery to a specific organ, rather than the bloodstream.

Silicon arrays of these piercing microstructures have been fabricated and having 4 μm high barbs and tested for gross adhesive capability. One-sided arrays, approximately 1 cm^2 square, were pressed into sections of a human vena cava obtained from a cadaver. The samples successfully bonded to the tissue, but the tensile strength is, as yet, below that required for clinical application. Electron micrographs of delaminated tissue showed four distinct regions which were characterized by several features. Holes occurred where the barbs penetrated and retracted from the tissue. Some barbs broke where penetration and bonding took place, but the silicon pedestal supporting the pointed cap failed. Intact pieces of silicon bonded to the issue. The silicon substrate itself fractured, probably during insertion. The epithelial lining separated from the vessel wall, with the microstructure arrays remaining bonded to the lining.

From this test it became clear that the barbs need to have a scale comparable to the thickness of the vessel wall for satisfactory bonding. It is preferred to have structures on the order of 50 to 100 μm high, or greater.

Although the structures of the invention were made using a photolithographic process other techniques could be used. For example, micromachining,

crystal growing methods, vapour deposition, particle beam manufacturing and other techniques for creating microstructures are possibilities.

Claims

1. A fastener for reconnecting a severed blood vessel or for closing a partially severed blood vessel (21,22), the fastener comprising:
   a. a female member (4) adapted to conform to an inner wall (20) of the blood vessel (21,22), the female member (4) having an outer surface (5) and an inner surface;
   b. a male member (2) adapted to conform to an inner wall (20) of the blood vessel (21,22), the male memebr (2) having a first outer surface portion (9) sized and positioned to engage the inner surface of the female member (4) and also having a second outer surface portion (6);
   c. a plurality of barbs (10) sized to pierce and anchor in the wall (20) of the blood vessel wall (21,22) the barbs (10) being attached to and extending from the outer surface (5) of the female member (4) and being attached to and extending from the second outer surface portion (6) of the male member (2);
   d. a first fastening means (16) attached to the inner surface of the female member (4); and
   e. a second fastening means (18,19) attached to the first outer surface portion of the male member (2), the first and second fastening means (16,18) being sized and configured to engage one another to lock the male member (2) to the female member (4).

2. A fastener according to claim 1 wherein the first fastening means (16) comprises a plurality of hemispherical projections (16) and the second fastening means (18,19) comprises a plurality of projections having a stem (19) and pod (18), each pod (18) being sized to fit within a hemispherical projection (16).

3. A fastener according to claim 1 or claim 2 wherein the male member (2) and the female member (4) are formed from a flexible material whereby they can be rolled into a diameter smaller than that of the blood vessel (21,22) inserted into the blood vessel (21,22) and unrolled to engage the inner wall (20) of the blood vessel (21,22).

4. A fastener according to claim 1 or claim 2 wherein the male member (2) and the female member (4) are compressible to a diameter smaller than that of the blood vessel (21,22) whereby they can be inserted into the blood vessel (21,22) in a compressed condition and there allowed to expand and anchor the male member (2) and the female member (4) to the inner wall (20) of the blood vessel (21,22).

5. A fastener for reconnecting a severed blood vessel, the fastener comprising a ring (36) sized and adapted to conform to splayed ends of a severed blood vessel (21,22) which ring (36) is provided on each of its opposed outer surfaces with a plurality of barbs (37) attached to and extending from the said outer surfaces, the barbs (37) being sized and configured to pierce and anchor in the wall of the blood vessel (21,22).

6. A fastener for reconnecting a severed blood vessel or for closing a partially severed blood vessel (21,22), the fastener comprising a sheet (30) provided on one of its surfaces (32) with a plurality of barbs (10) attached to and extending from the said surface (32), the sheet (30) being formed from a flexible material whereby it can be rolled into a diameter smaller than that of the blood vessel (21,22), inserted into the blood vessel (21,22) and unrolled to enagage the inner wall (20) of the blood vessel (21,22) with the barbs (10) piercing and anchoring in the said inner wall (20).

7. A fastener for reconnecting a severed blood vessel or for closing a partially severed blood vessel (21,22), the fastener comprising a sheet (30) provided on one of its surfaces (32) with a plurality of barbs (10) attached to and extending from the said surface (32), the sheet (30) being formed from a flexible material whereby it can be wrapped around the outside of the blood vessel (21,22) with the barbs piercing and anchoring in the outer wall (26) of the blood vessel (21,22).

8. A fastener according to any preceding claim wherein the barbs (10,37) extend 50 μm to 100 μm from the outer surface.

9. A fastener according to any preceding claim wherein the barbs (10,37) contain a passageway (46) through which a fluid may flow from a reservoir.

Fig.1.

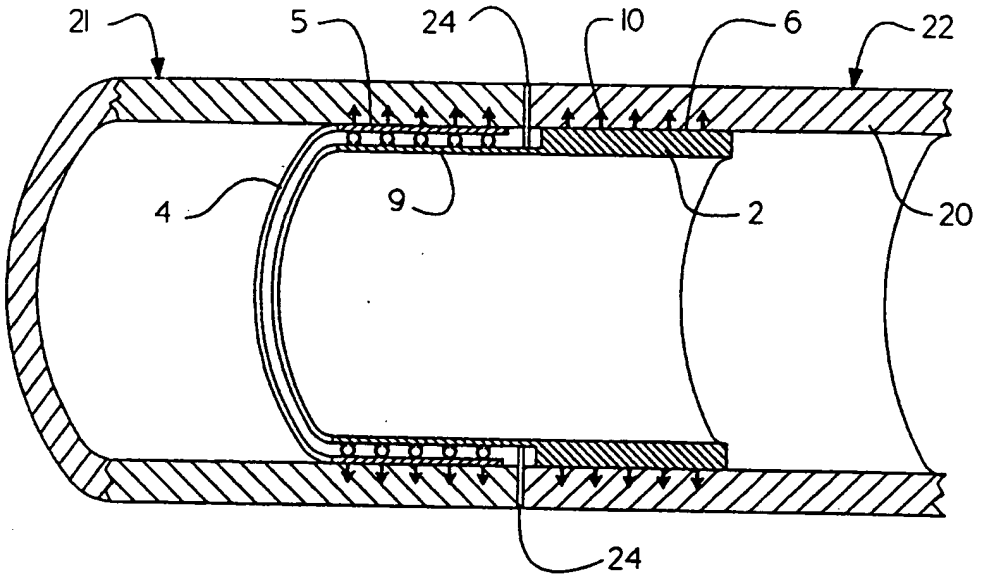


Fig.2.

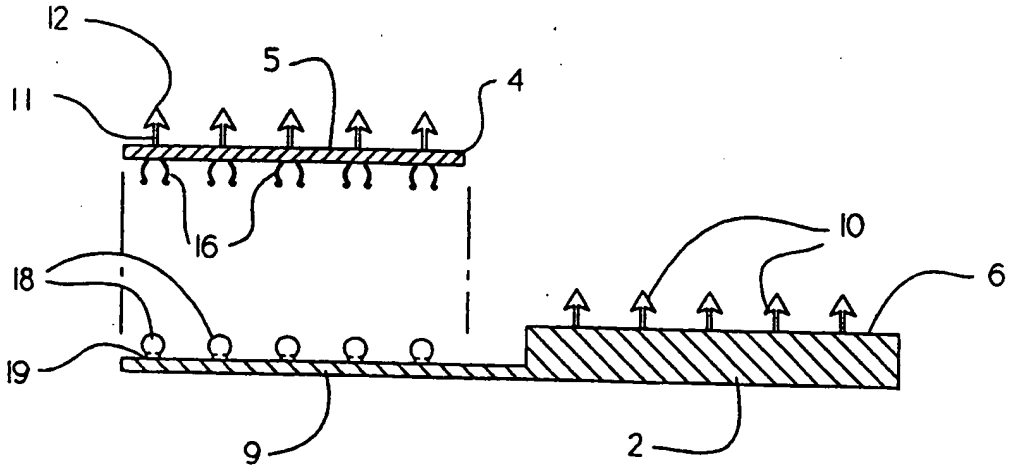


Fig.3.

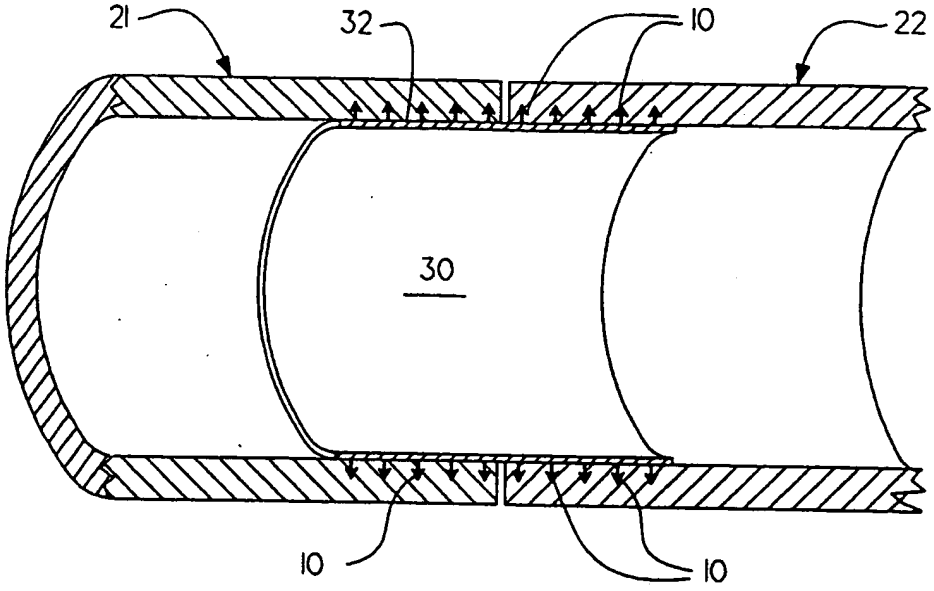


Fig.4.

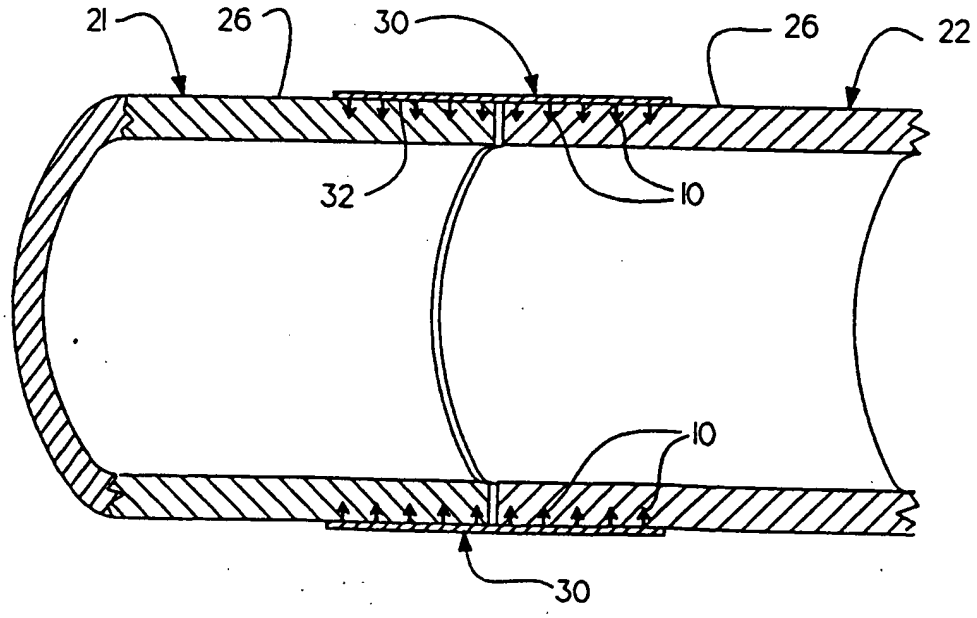


Fig.5.

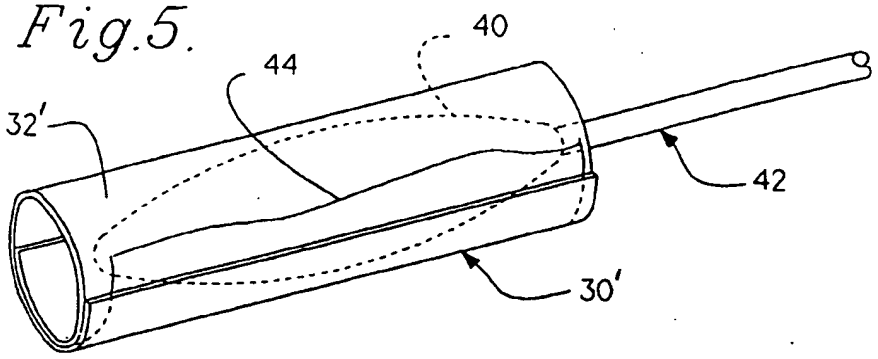


Fig.6.

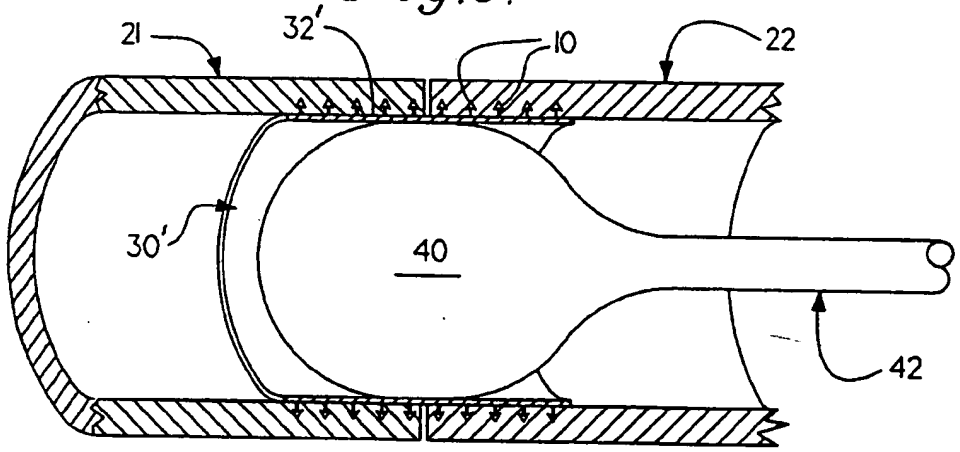


Fig.10.

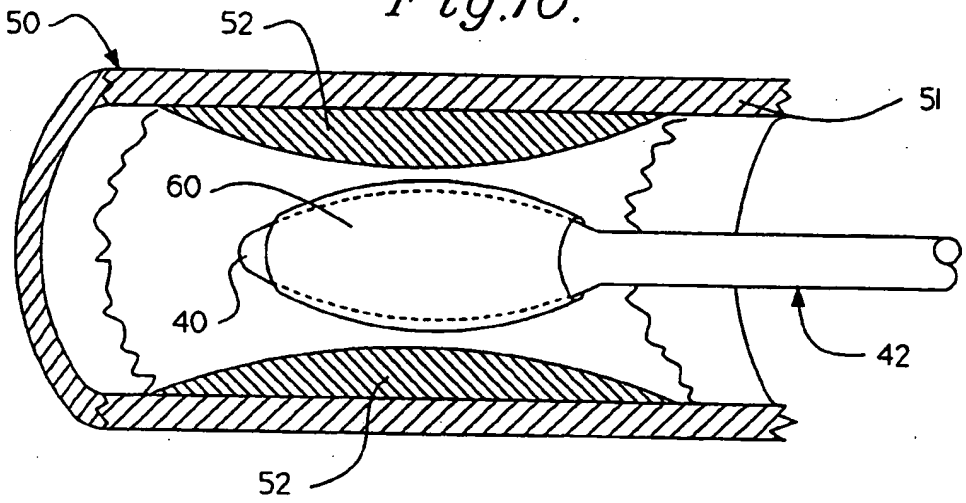


Fig.7.

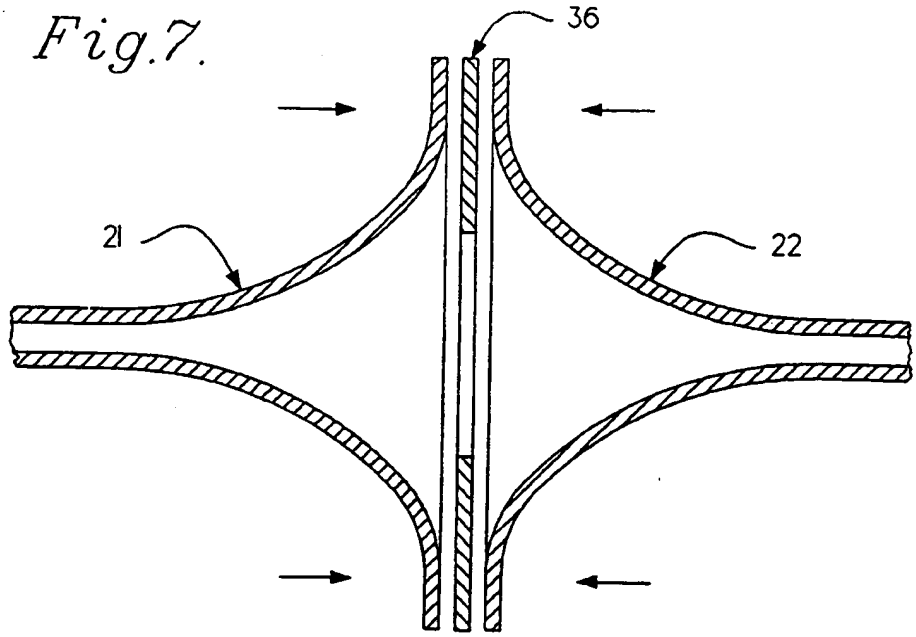
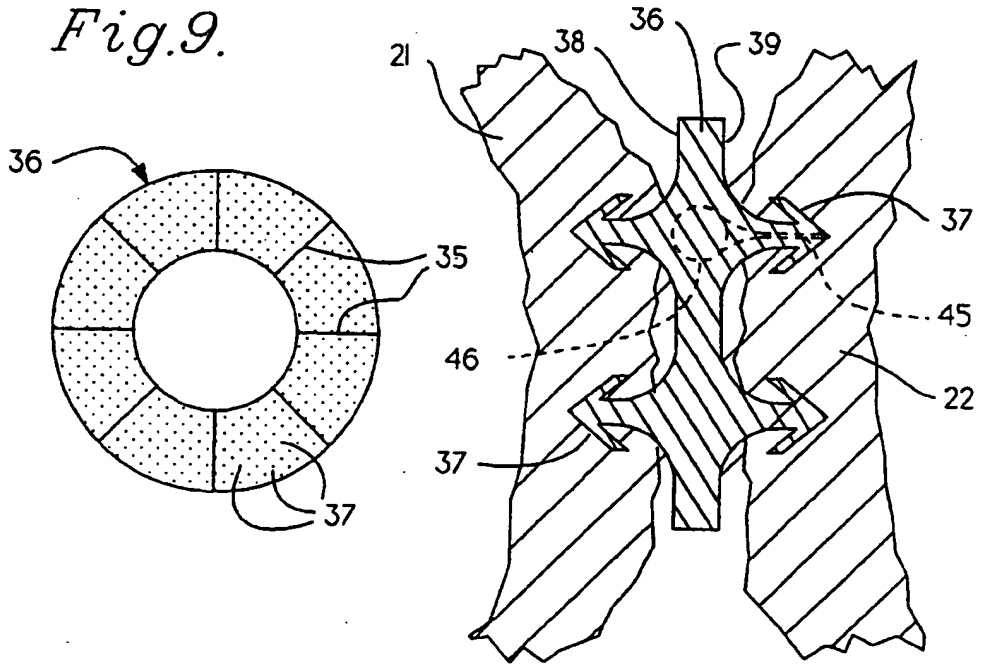


Fig.8.

Fig.9.



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EUROPEAN SEARCH REPORT

Application Number EP 93301512.5

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Y	US - A - 3 221 746 (J.W. NOBLE) * Totality *	6	A 61 B 17/11
Y	GB - A - 1 205 743 (NAT. RES. DEV.) * Totality; especially fig. 4; page 3, lines 58-63 *	6	
Y	EP - A - 0 442 657 (C.R. BARD INC.) * Fig. 1A,B; column 5, lines 5-11,16-30 *	6	
Y	US - A - 5 078 726 (J.W. KREAMER) * Fig. 2,3; column 2, lines 35-59 *	6	
Y	US - A - 5 059 211 (R.S. STACK et al.) * Fig. 5,6; abstract; column 4, lines 27-50 *	6	TECHNICAL FIELDS SEARCHED (Int. Cl.5)
A	US - A - 4 997 439 (F.H. CHEN) * Totality *	5	A 61 B A 61 M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
VIENNA	23-06-1993	LUDWIG

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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